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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,428	10/15/2001	Peter Unger	B0048-US02	5257

24994 7590 10/23/2002

GAMBRO, INC
PATENT DEPARTMENT
10810 W COLLINS AVE
LAKEWOOD, CO 80215

EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,428

Applicant(s)

Unger et al.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 22, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Oct 15, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/125,270.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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1. Applicant's election with traverse of Group I (claims 1-11) in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the mere conjecture of a different process such as separating various oil components does not by itself describe how or whether such a process is "materially different" from the claimed process. This is not found persuasive because the claimed apparatus can be used to practice another and materially different process such as washing red blood cells as evidenced by U.S. Patent No. 5,114,396. However, examiner agree that the application's argument against the restriction requirement of combination and subcombination of Group II (claims 12-19) and Group III (claim 20) is persuasive and therefore, Group II and Group III are rejoined but still restricted from Group I.

2. Claims 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 4.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite for failing to particularly point out whether a processing bag is placed in a centrifuge to be centrifuged.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by WO95/01842. WO95/01842 teaches a method of separating cells in a centrifuge comprising providing buffy coat in a processing bag (1) in a centrifuge, separating cells into thrombocyte-rich plasma (i.e. light-weight fraction enriched with platelets), transferring thrombocyte-rich plasma to a storage bag (2) via an outlet tube (3) having an opened clamp valve (38) responding to the programmed operation of the centrifuge and/or photocells which detect the displacement of the boundary surface of the phase in the outlet tube (3) wherein buffy coat inherently includes platelets and red blood cells (see page 8, line 29 - page 10, line 31).

8. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/01842. WO95/01842 teach clamp valve (38) responding to the programmed operation of the centrifuge and/or photocells which detect the displacement of the boundary surface of the phase in the outlet tube (see page 9, lines 4-11). Manual clamps and/or electromagnetic activatable valves are well-known in the art to control the flow of the fluid. It would have been

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obvious to a person of ordinary skill in the art to employ Manual clamps and/or electromagnetic activatable valves in the outlet tube in the method of WO95/01842 to control the flow of enriched fraction to a storage bag.

9. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/01842 as applied to claim 1 above, and further in view of U.S. Patent No. 4,010,894 (Kellog et al.).

Claims 4-6 essentially differ from the method of WO95/01842 in reciting the step of transferring enriched fraction through a first radially portion of the outlet tube having a radially inwardly directed flow including diverting the radial flow into a peripheral flow via a cell trap having an enlarged section for maintaining specific cells and a second radially positioned portion of the tube having a radially outwardly directed flow. Kellog et al teach a method for transferring enriched fraction through an outlet tube (11) having a first radially portion of the outlet tube having a radially inwardly directed flow (via 19 or 21 from 17) including diverting the radial flow into a peripheral flow (around 11) via a cell trap (17) having an enlarged section for maintaining specific cells and a second radially positioned portion of the tube having a radially outwardly directed flow (near 25) (see col. 2, line 17 - col. 3, line 16). It would have been obvious to a person of ordinary skill in the art to employ above outlet tube with two radially portion in the method of WO95/01842 for improving the selective separation of blood to different fractions.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,114,396 and 4,990,132 and 4,950,401 and 3,326,458 and 3,679,128

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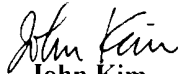
and 5,160,310 and 5,316,540 and 6,348,031 and 5,723,050 and 6,261,217 and 5,674,173 and WO 87/06857 teach the centrifugal separation of biological fluid.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
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J. Kim
October 18, 2002